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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,510	04/19/2004	Stefan Zimmermann	313S-300710US	4303

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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
11/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,510	ZIMMERMANN ET AL.	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-38* is/are pending in the application.

4a) Of the above claim(s) *29-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20-28 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The oath presently states "duty to disclose information which is material to the examination of this application". This statement should read --duty to disclose information which is material to patentability of this application--.

Claim Rejections - 35 USC § 112

3. Claims 1-28 and 38-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-28 and 38-39 reference "out-of-plane" microneedles, but no definition of this is provided, nor is it a term commonly known in the art. For examination

purposes, the invention will be considered to have as a plane the flat surface from which microneedles protrude (thereby being "out-of-plane").

Though the term is used repeatedly in the specification, there is no clear explanation of its meaning. The drawings do not clearly illustrate what makes the needles "out-of-plane", nor does any part of the specification or drawings define what plane the needles are "out of". The term is not common to the art, being present only in other patents and applications from the same inventors and/or assignee as the present application, and one of ordinary skill in the art, unless associated with the present assignee or inventors, would not enable one to make the invention.

Claim Rejections - 35 USC § 102

4. Claim 38 is rejected under 35 U.S.C. 102(b) as being anticipated by Park (US Patent Application Publication 2002/0082543).

Park discloses a method of monitoring one or more substances of interest (paragraph [0002]) comprising applying a plurality of microneedles to a surface of an internal region (paragraphs [0034]-[0035], [0057]) where the microneedles are long enough to prestress a region of the surface; applying pressure to the surface via the microneedles to cause cell disruption (paragraphs [0047]-[0048], [0057]) so that the contents of the cell may enter the microneedle's lumen; and using the connection between the cell contents and needle contents to sample the substances at and/or just below the surface (paragraphs [0076]-[0077], [0129]-[0131]).

Claim Rejections - 35 USC § 103

5. Claims 1-4, 6, 7, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonnelli'158 (US Patent Application Publication 2003/0135158) in view of Sage (US Patent Application Publication 2003/0143746).

Regarding claim 1, Gonnelli'158 discloses a method of monitoring a substance of interest (paragraphs [0003], [0053], [0055]) comprising applying a plurality of microneedles to a surface of an internal region (paragraphs [0027], [0037]) where the microneedles are long enough to sample a substance of interest at and/or just below the surface (paragraphs [0028], [0036]); where the microneedles comprise one or more membranes (element 140) on a side opposite a side applied to the surface such that the membrane is not placed under the surface (figure 1B). Gonnelli'158 does not teach using the membrane to separate the microneedles from a dialysis material in order to perform dialysis outside the internal region.

Sage teaches a method of monitoring a substance of interest using a microneedle that has a membrane (element 12) separating the implanted structure from a dialysis fluid (paragraph [0028]), in order to perform dialysis in a minimally invasive fashion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the method of Gonnelli'158 with the membrane separating the microneedles from a dialysis material, as taught by Sage, in order to perform dialysis in a minimally invasive fashion.

Regarding claims 2 and 39, Gonnelli'158 discloses a method of monitoring a substance of interest (paragraphs [0003], [0053], [0055]) comprising applying a plurality

of microneedles to a surface of an internal region (paragraphs [0027], [0037]) while keeping a membrane and a fluid outside of the region (paragraph [0059]). Though Gonnelli'158 teaches passing substances into and out of the body (a description that applies to dialysis - paragraphs [0032], [0051]), Gonnelli'158 does not specifically disclose using a dialysis membrane and dialysis fluid during the monitoring.

Sage teaches a method of monitoring a substance of interest using a microneedle (element 3), a dialysis membrane (element 12), and a dialysis fluid to conduct dialysis (paragraph [0028]), in order to conduct dialysis in a minimally invasive fashion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the method of Gonnelli'158 with a dialysis membrane and dialysis fluid, as taught by Sage, in order to perform dialysis in a minimally invasive fashion.

Regarding claim 3, the membrane surface of Gonnelli'158 in view of Sage may be considered "large", and it remains outside the internal region, as discussed above.

Regarding claim 4, Gonnelli'158 further discloses that the surface may be the skin of a mammal (paragraph [0003]).

Regarding claim 6, Gonnelli'158 further discloses that the surface may be a surface of a living organism or a part or organ thereof (paragraph [0003]).

Regarding claim 7, Gonnelli'158 further discloses that the microneedles may be pre-filled with a fluid before application (paragraph [0054]).

6. Claims 8, 10-12, and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sage in view of Gonnelli'158.

Regarding claim 8, Sage discloses a method of treating glucose disorders comprising applying needles and a dialysis membrane to the skin of a subject (paragraphs [0028]-[0029]) and performing continuous glucose monitoring by testing the composition of a dialysis fluid that is separated from the needle by the membrane (paragraphs [0017]-[0018], [0031]-[0032]). Sage does not teach using a microneedle for contacting the skin, nor the dialysis membrane remaining outside the skin.

Gage teaches a method of obtaining fluids from a subject's skin comprising using a group of microneedles (elements 112) and a membrane located on the non-inserted side of the group (element 140, figure 1B), in order to increase the surface area of the monitored surface while reducing the required size of the microneedles used by eliminating the membrane's presence from the inserted component. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Sage and used a plurality of microneedles and the dialysis membrane opposite the insertion surface, as taught by Gonnelli'158, in order to increase the surface area of the monitored surface while reducing the required size of the microneedles used by eliminating the membrane's presence from the inserted component.

Regarding claim 10, Sage discloses a device for monitoring a substance comprising a microneedle (element 3), a dialysis membrane (element 12), and a dialysis fluid in contact with the side of the membrane not exposed to a surface of interest (paragraph [0028]); so that when pressed against the surface, the substance of interest

can pass through the microneedle and dialysis membrane into the dialysis fluid (paragraph [0029]). Sage does not disclose a plurality of microneedles, or the membrane being proximal to the non-inserted side of the group of microneedles.

Gonnelli'158 teaches a device that may be used to monitor a substance comprising a group of microneedles (elements 112) and a membrane located on the non-inserted side of the group (element 140, figure 1B), in order to increase the surface area of the monitored surface while reducing the required size of the microneedles used by eliminating the membrane's presence from the inserted component. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Sage with a plurality of microneedles and the dialysis membrane opposite the insertion surface, as taught by Gonnelli'158, in order to increase the surface area of the monitored surface while reducing the required size of the microneedles used by eliminating the membrane's presence from the inserted component.

Regarding claims 11 and 19, Sage further discloses one or more sensors in contact with the dialysis fluid for measuring and/or detecting the substance of interest (paragraph [0031]).

Regarding claim 12, Sage further discloses a an area for holding calibration fluid (element 22) and a valve between the calibration fluid and the dialysis fluid (paragraph [0034]).

Regarding claim 17, Gonnelli'158 further teaches that the membrane may comprise at least one membrane that separates a plurality of microneedles from fluid

(paragraph [0041]), in order to allow separate monitoring of adjacent areas. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Sage in view of Gonnelli'158 with the membrane comprising one or more membranes, each separating a plurality of microneedles from dialysis fluid, as taught by Gonnelli'158, in order to allow separate monitoring of adjacent areas.

Regarding claim 20, Gonnelli'158 further teaches that the microneedles may be between about 100 and 300 micrometers long (paragraph [0035]), in order to reach the substances of interest without penetrating too deep. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Sage in view of Gonnelli'158 with the microneedles between about 100 and 300 micrometers long, as taught by Gonnelli'158, in order to reach the substances of interest without penetrating too deeply.

Regarding claim 21, Gonnelli'158 further teaches that the microneedles may be between about 180 and 220 micrometers long (paragraph [0035]), in order to reach the substances of interest without penetrating too deep. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Sage in view of Gonnelli'158 with the microneedles between about 180 and 220 micrometers long, as taught by Gonnelli'158, in order to reach the substances of interest without penetrating too deeply.

Regarding claim 22, Gonnelli'158 further teaches that the microneedles may be made of a metallic material (paragraph [0031]), since the use of metallic materials for microneedles is well-known in the art. It would have been obvious to one of ordinary

skill in the art at the time the invention was made to have made the device of Sage in view of Gonnelli'158 with metallic microneedles, as taught by Gonnelli'158, since the use of metallic materials for microneedle composition is well-known in the art.

Regarding claim 23, Gonnelli'158 further teaches that the microneedles may be made of plastic (polymers - paragraph [0031]), since the use of plastics for microneedles is well-known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Sage in view of Gonnelli'158 with plastic microneedles, as taught by Gonnelli'158, since the use of plastics for microneedle composition is well-known in the art.

Regarding claim 24, Sage further discloses that the microneedles may be made of silicon (paragraph [0029]).

Regarding claim 25, Gonnelli'158 further teaches that the microneedles may be made of a semiconductor material (paragraph [0031]), since the use of semiconductors for microneedles is well-known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Sage in view of Gonnelli'158 with semiconductor microneedles, as taught by Gonnelli'158, since the use of semiconductors for microneedles is well-known in the art.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gonnelli'158 in view of Sage, as applied to claims 1, 2, 4, 6, 7, and 39 above, and further in view of Berner (US Patent Application Publication 2001/0016682).

Gonnelli'158 in view of Sage discloses all the elements of the current invention, as described above, except for the surface being that of a plant. Berner teaches a method of monitoring a substance using microdialysis where the surface from which the substance is measured may be that of a plant (paragraph [0034]), since it is well-known in the art that dialysis may be used to monitor substances within plants in addition to animals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the method of Gonnelli'158 in view of Sage to monitor a substance of interest from a part of a plant, as taught by Berner, since it is well-known in the art that microdialysis may be used to monitor substances from plants.

8. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sage in view of Gonnelli'158, as applied to claims 10-12 and 19-25 above, and further in view of Whitson (US Patent Application Publication 2002/0006355).

Regarding claims 13-15, Sage in view of Gonnelli'158 discloses all the elements of the current invention, as described above, except for the specific number of microneedles contained within the microneedle array. Whitson teaches a microneedle array composed of at least 200 microneedles (paragraph [0023]), in order to cover a desired surface area. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Sage in view of Gonnelli'158 with at least 200 microneedles, as taught by Whitson, in order to cover a desired surface area.

Regarding claim 16, the Examiner notes that Whitson does not expressly disclose the device comprising at least 750 microneedles. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use at least 750 microneedles because the Applicant has not disclosed that the use of 750 microneedles provides a particular advantage, is for a particular purpose, or solves a stated problem. Moreover, it appears that Whitson's 400 microneedles and Applicant's 750 microneedles would perform dialysis equally well. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Sage in view of Gonnelli'158 and Whitson such that the device comprised at least 750 microneedles, because such a modification would have been considered a mere design consideration that fails to patentably distinguish over Sage in view of Gonnelli'158 and Whitson.

9. Claims 18 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sage in view of Gonnelli'158, as applied to claims 10-12 and 19-25 above, and further in view of Gonnelli'201 (US Patent Application Publication 2003/0135201).

Regarding claim 18, Sage in view of Gonnelli'158 discloses all the elements of the current invention, as disclosed above, except for the dialysis membrane comprising a plurality of membranes where at least some of the membranes provide separation for an individual microneedle.

Gonnelli'201 teaches a device for monitoring a substance of interest comprising microneedles having a membrane that may be located on the non-insertive surface

(paragraph [0010]), where the device may comprise a plurality of membranes (figure 5; paragraph [0085]), some of which are used with only one microneedle (figure 3), in order to perform different tasks during dialysis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Sage in view of Gonnelli'158 with a plurality of dialysis membranes, some of which are used with a single microneedle, as taught by Gonnelli'201, in order to perform different tasks during dialysis.

Regarding claim 26, Sage in view of Gonnelli'158 discloses all the elements of the current invention, as disclosed above, except for the membrane comprising a polymer, gel, and/or porous poly-Si.

Gonnelli'201 teaches a device for monitoring a substance of interest comprising microneedles having a membrane that may be located on the non-insertive surface (paragraph [0010]), where the membrane may be formed of a polymer (paragraph [0062]), since use of polymers as selective membranes is well-known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Sage in view of Gonnelli'158 with a polymer membrane, as taught by Gonnelli'201, since use of polymer dialysis membranes is well-known in the art.

Regarding claim 27, Sage in view of Gonnelli'158 discloses all the elements of the current invention, as disclosed above, except for the membrane comprising integrated enzymes.

Gonnelli'201 teaches a device for monitoring a substance of interest comprising microneedles having a membrane that may be located on the non-insertive surface (paragraph [0010]), where the membrane may be formed of an ion-selective substance such as NAFION™, which may contain enzymes (paragraph [0065]), in order to increase the membrane's selectivity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Sage in view of Gonnelli'158 with a membrane integrating enzymes, as taught by Gonnelli'201, in order to increase the membrane's selectivity.

10. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sage in view of Gonnelli'158, as applied to claim 10 above, and further in view of Skrabal (US Patent 5097834).

Sage in view of Gonnelli'158 discloses all the elements of the claimed invention, as disclosed above, and also discloses a check valve (element 5), but does not disclose the check valve working with another diffusion barrier to serve as a two-way valve. Skrabal teaches a sensing device comprising a diffusion barrier (element 24) working with a one way valve (element 25) to serve as a two-way valve controlling which fluid passes through a part of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included an additional diffusion barrier, as taught by Skrabal, in the system of Sage and Gonnelli, in order to control the flow of fluids and prevent back-flow.

Allowable Subject Matter

11. Claim 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the method of claim 9, including, *inter-alia*, treating glucose disorders using microneedles and performing dialysis, fixing a substance that measures glucose levels on the non-needle side of a dialysis membrane, and performing the fixing by placing a polymer-detecting substance solution on the membrane after the microneedles have been fabricated and/or assembled.

Response to Arguments

12. Applicants arguments regarding claim 8 are moot in view of the new grounds of rejection. Applicant's additional arguments filed 13 August 2007 have been fully considered but they are not persuasive.

Regarding Applicant's arguments concerning Park and the claimed limitation of applying high pressure through the microneedles, Applicant has not defined a range or value for "high" pressure – as such, any method of glucose monitoring that involves pressing microneedles into the skin (that is, applying pressure through the microneedles), such as Park, anticipates the claim. Further, in the remarks Applicant describes the claimed invention as applying pressure through the lumen, but the claim merely states that pressure is applied "through [the] microneedles" in order to form a

connection between cell matrix fluids and lumen fluids; in the broadest reasonable interpretation of the claim language, it may be interpreted as applying pressure that is translated through the needles to the body, where the applied pressure causes the desired cell rupture. Applicant could overcome this rejection by clarifying that the pressure is delivered through the lumen of the microneedles.

Regarding Applicant's argument that Sage teaches away from the claimed invention because the overall structure of sage includes a needle and membrane that are inserted into a body, Examiner disagrees. The only component of Sage incorporated in the present rejection is the membrane; since Gonnelli discloses a membrane, but does not disclose a particular type of membrane, Sage is incorporated to show that it is well known in the art to use a membrane for dialysis. The remaining structure of Sage is not pertinent to the present rejection, and, in fact, provides motivation for combining the two, since using Sage's membrane in Gonnelli's structure would in fact result in a less-invasive device, which would be beneficial to the user.

The rejections stand as FINAL.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5243982 to Mostl, which discloses similar inventions.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser/
Primary Examiner, Art Unit 3735

/K. E. T./